REMARKS

Claims 1, 4-28, and 31-57 are pending in the application.

Claims 5-28, 31-33, 37-49 and 53 have been withdrawn from further consideration as being drawn to unelected subject matter.

Claim 1 has been amended.

New claims 54-57 have been added.

Claims 2, 3, 29 and 30 have been cancelled without prejudice or disclaimer to the subject matter contained therein.

Applicants specifically retain the right to pursue the subject matter contained in any of the amended or cancelled claims in this or an appropriate divisional, continuation or continuation-in-part application(s).

The amendments and new claims do not include any new subject matter within the meaning of 35 U.S.C. §132. Therefore, entry of the amendments is respectfully requested.

1. Claim Rejection – 35 U.S.C. §112, second paragraph

The Examiner has rejected claims1-4, 29, 30, 34-36 and 50-52 as being indefinite for failing to particularly point out and distinctly claim the instant subject matter. The Examiner states that these claims "are incomplete for omitting essential steps" and has requested further clarification of the claims.

Applicants traverse this rejection.

Applicants respectfully submit that claim 1 has been amended to clarify the method steps involved in this claim and thereby overcomes the rejection. Furthermore, claims 34, 35 and 50-52 are dependent upon claim 1 and overcome the rejection, as such.

Claims 2, 3, 29 and 30 have been cancelled.

Claims 36 and 52 are directed to a diagnostic kit and a pharmaceutical composition, respectively, and therefore cannot be rejected on the grounds that they do not include essential method steps.

Applicants submit that claim 4 is definite in that it particularly points out and distinctly claims the subject matter Applicants regard as the invention.

Accordingly, the bases for this rejection have been removed, and Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

2. Claim Rejection – 35 U.S.C. §102(e)

The Examiner has rejected claims 1-4, 29, 30, 34-36 and 50-52 as being anticipated by Schlegel et al. in U.S. Published Patent Application No. 20030108963.

The Examiner states that the instant claims are drawn to a method of diagnosing prostate cancer comprising detecting a level of annexin A3 as compared to a control. The Examiner continues by stating that Schlegel et al . teach methods of detecting and diagnosing human prostate cancer, while disclosing diagnostic markers, including annexin A3 as particularly useful in both screening for the presence of prostate cancer, as well as, for metastatic potential of prostate cancer. The Examiner also states that Schlegel et al. disclose the use of antibodies which specifically bind to the marker proteins for diagnostic purposes and a kit.

The Examiner states Applicants argument that Schlegel et al. only disclose differential expression of annexin A3 RNA and as such fail to teach how annex A3 protein should be used as a diagnostic marker was deemed not persuasive.

Applicants traverse this rejection.

Schlegel et al. disclose the identification of differentially regulated RNA molecules in prostate tissue of prostate cancer patients versus. healthy prostate tissue. See, Schlegel et al., page 46, paragraphs [0309] and [0310]. The identified differentially regulated RNA molecules are listed in Tables 1-5 on pages 4-18 of Schlegel et al. Among those molecules there is also the RNA of annexin A3 in Tables 1-4. In paragraph [0011], Schlegel et al. describe that the nucleic acids and proteins listed in Tables 1-5 can be used as a marker for prostate cancer.

Contrary to the present subject matter, Schlegel et al. does not present any data regarding the actual regulation of annexin A3 protein. Schlegel et al. only refer to a differential regulation of the annexin A3 RNA in prostate tissue of healthy patients versus prostate cancer patients. However, Schlegel et al. does not teach how the annexin A3 protein is to be used as a diagnostic marker.

The subject matter of the present application, however refers to the annexin A3 protein as a diagnostic marker and shows that the annexin A3 protein is differentially regulated in prostate tissue versus healthy tissue. See, English translation of instant application, page 12, paragraph [0039], lines 1-5 and Table 1.

Further, the subject matter of the instant application differs from Schlegel et al. by the fact that, in Schlegel et al., there is no reference regarding a relation between annexin A3 and the diagnosis of subtypes of prostate cancer. Schlegel et al. solely deal with the identification of RNA markers for prostate cancer, in general. In contrast thereto, Applicants identified different prostate cancer subtypes a, b and c on the basis of the expression of different protein patterns which are specific for the respective prostate cancer subtype. See, English translation of instant application, pages 16-17, paragraphs [0048]-[0051] and Figures 3 and 4. Thus, Applicants submit that it could be shown that the expression of annexin A3 protein is regulated in a different way in the different prostate cancer subtypes. Thus, the prostate cancer subtypes a and c do not show any or only minor regulation of the expression of annexin A3 protein, whereas an upregulation of annexin A3 protein has been observed in the prostate cancer subtype b. The annexin A3 protein can therefore be used as a diagnostic marker for special patient subtypes or prostate cancer subtypes. No such teaching can be

found in Schlegel et al.

For these reasons, the instantly claimed subject matter is not anticipated by Schlegel et al.

Accordingly, the basis for this rejection has been removed, and Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

In further support of the patentability of the instantly claimed subject matter, Applicants hereby submit that they have shown that different prostate cancer subtypes can be identified by different protein expression patterns which are specific to the respective subtypes. Thus, an upregulation of annexin A3 protein is characteristic for prostate cancer subtype b, while subtypes a and c show no or only minor regulation of this protein. Applicants submit that this supports that a missing annexin A3 protein expression does not necessarily support a diagnosis that the patient is free from prostate cancer. For this reason, the analysis of annexin A3 protein expression may provide additional information of prostate cancer patients or in combination with general cancer markers. Within the various protein expression patterns, there are the so-called "general cancer markers" which are up- or downregulated in all prostate cancer subtypes when compared to healthy samples. For example, heat shock proteins 27 and 90, the enoyl coenzyme A hydratase, the ubiquitin isopeptidase T and the protein disulphide isomerase. These proteins can be found at the intersection which is formed by the three prostate cancer subtypes and provide a general reference to each of the subtypes. See, English translation of instant application, Figure 3.

Therefore, by means of the instantly claimed subject matter, the respective prostate cancer subtypes identified herein can be diagnosed. However, Applicants submit that this also shows that all prostate cancers are not identical based necessary fact that the different protein expression patterns in the respective subtypes indicate different molecular processes within each subtype. This may lead to the development of specifically tailored therapies for the respective patient groups, which would take into consideration the corresponding specific molecular processes. Therefore, Applicants submit that on the basis of the instantly claimed subject matter, the specific treatment of certain subtypes of prostate cancer is enabled. This has not been shown by Schlegel et al.

As stated above, Schlegel et al. teaches the differential expression of specific RNA molecules in the prostate tissue of prostate cancer patients versus healthy patients. Schlegel et al. teach a general upregulation of annexin A3 RNA in prostate tissue of prostate cancer patients and conclude

that both annexin A3 RNA and the protein can be used as a diagnostic marker for prostate cancer. See, Schlegel et al. page 1, paragraph [0011] and Table 1. Based on this teaching of upregulation of annexin A3 RNA or protein by Schlegel et al., one would expect that when such an upregulation is observed in a patient, then the patient suffers from prostate cancer. However, this teaching is in direct opposition to the findings of Applicants which show that other expression patterns for the annexin A3 protein in prostate cancer tissue can occur. As previously explained, Applicants observe that when analyzing annexin A3 protein, the presence of prostate cancer does not automatically involve an upregulation of this protein, since the protein is only upregulated by some of the prostate cancer groups while in others no regulation of the protein can be observed. As such, this observation better enables a more accurate diagnosis of the subtypes of prostate cancer and subsequently a more tailored therapy.

For theses reasons, Applicants submit that based on the teachings of Schlegel et al., one would not arrive at the instantly claimed subject matter.

As such, the instant subject matter is patentable of Schlegel et al.

CONCLUSION

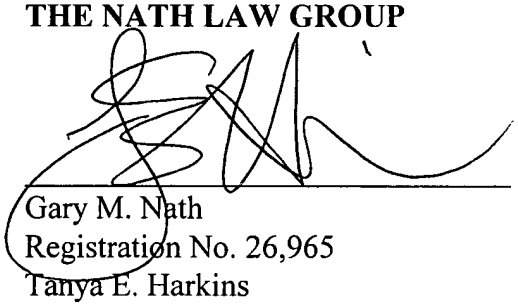
In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the outstanding rejection and to allow all of the claims pending in this application.

Applicants respectfully request that the Examiner contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



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